

REMARKS

Claims 1-26 are pending. Claims 1-23 have been rejected, and claims 24-26 have been stated to be allowable if placed in independent form.

For the convenience of the Examiner, the following appendices and exhibits are attached hereto:

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| Appendix A: | Table of claims as filed and amended in application of original patent |
| Appendix B: | Table comparing claims of original patent with claims as filed and amended in reissue application |
| Exhibit 1: | <i>Ex parte Danby</i> , 58 USPQ2d 1093 (BPAI 0000) |
| Exhibit 2: | <i>Ex parte Eggert et al.</i> , No. 2001-0790, slip op. (BPAI June 12, 2001) |

Supplemental Reissue Declaration

Pursuant to 37 CFR 1.175, applicants enclose a Supplemental Reissue Application Declaration By All Inventors, updating and verifying that all errors being corrected arose without any deceptive intent.

Information Disclosure Statement

Applicant acknowledges the changes made by the Examiner to the Information Disclosure Statement filed December 6, 2001. *See*, Office Action, paragraph 1. It is Applicants' understanding that the Examiner has himself entered the changes, and that it is unnecessary for Applicants to submit a substitute Form 1449. If this is not the case, please inform the undersigned.

Claim 1

Claim 1 was amended in the Preliminary Amendment of December 6, 2001, submitted with the current reissue application, in part by deleting the phrase "...for use in the detection of the test sample and sealed," which phrase merely stated an intended use of the claimed device and is not considered essential to patentability. See, Preliminary Amendment dated December 6, 2001, page 6. Applicants acknowledge and appreciate that the Examiner did not object to deleting this phrase.

Claim 21

Claim 21 (claim 73 as filed) is amended herein to place it in the form that the prosecution history reflects would have been allowable absent error by the prosecuting attorney. During prosecution of the original patent, claim 21[73] was not subject to any prior art rejections; in particular, claim 21[73] was not included in any of the rejections over Matsumoto et al. and/or Bernstein et al. The only rejection made against patent claim 21[73] was for double patenting, which rejection was overcome by a terminal disclaimer. Once properly disclaimed, patent claim 21[73] would have been allowable in its originally-filed form had it merely incorporated the language of claim 51 as filed in the Preliminary Amendment of November 27, 1995. Unfortunately, when the prosecuting attorney amended patent claim 21[73] to place it in independent form (see Amendment of April 17, 2000), he narrowed the claim far more than necessary. He incorporated not only the original limitations of claim 51, but also the limitations that were being newly added to claim 51 on even date. The extra limitations added to claim 21[73] in the Amendment filed April 17, 2000, were patentably unnecessary, and the prosecuting attorney thus erred by over limiting the claim. Accordingly, reissue claim 21 is amended herein to

restore it to the language stated, during the original prosecution, to be allowable pending disclaimer.

Rejection under 35 U.S.C. § 112, ¶ 2

Claims 3-6 and 10-13 have been rejected under 35 U.S.C. § 112, 2nd paragraph, as being indefinite on various grounds, as addressed below.

Claim 3 is amended to clarify that the reagent composition is a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing.

Claim 4 is amended to clarify that the reagent composition is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; (ii) a reaction stopping solution having a pH of 8 to 11; and (iii) a luciferin-luciferase or phosphatase substrate reagent. The presence of a pH indicator does not materially affect the basic characteristic of the claimed composition. It is consistent with the language being further limited, where such language includes i) "buffered;" and ii) "a pH of 8 to 11."

Claim 5 is amended to clarify that the reagent composition present in the chamber is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; and (ii) a reaction stopping solution having a pH of 8 to 11.

Claim 6 is amended by deleting the words "to carry out the test." The amendment is made to make the claim more definite, as the phrase "to carry out the test" is not regarded as being

material to patentability. Claim 6 is further clarified by replacing “test apparatus includes” with “test apparatus further comprises.”

Claim 10 is amended to clarify that the reagent composition present in the chamber is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; and (ii) a reaction stopping solution having a pH of 8 to 11, and that the luciferin and luciferase reagent is at the bottom of the test apparatus.

Claim 11 is amended to depend from claim 6, as suggested by the Examiner. Claim 11 is further clarified by replacing “test apparatus includes” with “test apparatus further comprises.”

Claim 12 is amended to clarify that the reagent composition present in the chamber is selected from the group consisting of i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; ii) a reaction stopping solution having a pH of 8 to 11; and iii) a luciferin-luciferase or phosphatase substrate reagent.

Claim 13 incorporates the limitations of claim 12, from which it depends.

Withdrawal of the rejection of claims 3-6 and 10-13 under 35 U.S.C. § 112, 2nd paragraph, is respectfully requested.

Rejection under 35 U.S.C. § 251

Claims 1-23 have been rejected under 35 U.S.C. § 251 as being an improper recapture of surrendered subject matter. The rejection is respectfully traversed. Omitting 'tablet' from the reissue claims does not pose a recapture problem.

The record shows that neither Applicants nor the Examiner considered the 'tablet'

limitation to be patentably material or to be necessary to overcome the prior art. The Examiner correctly observes that "Applicants made no argument on the record that the tablet limitation was added to obviate the rejection." *Office Action*, August 14, 2002, page 5. In fact, the opposite is true: according to the prosecution record, the prosecuting attorney thought the 'tablet' limitation had been met by the prior art itself.

The Board of Patent Appeals and Interferences (hereinafter "the Board") in view of controlling precedent of the Court of Appeals of the Federal Circuit ("Federal Circuit"), has declined to apply the recapture rule in situations similar to the one presented here. *Ex parte Danby*, 58 USPQ2d 1093, 1096 (BPAI 2000)(‘in parallel planes’ limitation not regarded as surrendered subject matter where it was unnecessary to secure allowance); *Ex parte Eggert et al.*, No. 2001-0790, slip op. at 25, 26, 29 (BPAI 6/12/2001)(declining to apply the recapture rule where claims were broader only in aspects unrelated to the prior art rejection at issue; although omitted limitations broadened the reissue claims relative to surrendered subject matter, limitations were not argued during prosecution to distinguish over the art, and the same limitations were met by the primary prior art reference itself).

I. The Intrinsic Record

Portions of the intrinsic record relating to the broadened subject matter, including changes to the claims, admissions, and arguments made by the former prosecuting attorney, Mr. Richard P. Crowley, Esq., are summarized below.

A. Prosecution of the Reissue Application

The current reissue application was filed on December 6, 2001, well in advance of the two-year period permitted for seeking a broadening reissue. Reissue is sought, in part, to broaden

claims 1, 10, 14, 19, 21, and 23 by removing the word 'tablet,' so as to clarify that the form of the recited reagent composition(s) may be any of the forms disclosed in the specification. Omission of the 'tablet' limitation is supported by the original specification as a whole, and in particular at column 3, lines 62-65 ("...which may be solid, liquid, powder, emulsion, suspension, tablet or substantially any combination separately or admixed thereof."). Preliminary Amendment, December 6, 2001.

B. Prosecution of the Original Patent

On January 30, 2001, original patent U.S. 6,180,395 issued from application Serial No. 09/396,127, which had been filed on September 14, 1999, accompanied by a preliminary amendment canceling claims 1-50 and adding new claims 51-73. Claims 54, 55, 65, 67, and 72 were amended, and claims 76-79 were added, by an amendment dated April 17, 2000. Claims 51-53, 56-64, 66, 68-71, and 73-78 were allowed on June 5, 2000, without further amendment. Appendix A, attached hereto, compares the originally-filed claim language with the claim language as amended, allowed, and issued.

(a) Applicant Admissions. In the specification, Applicants disclosed that the reagent composition could be provided in any of several equivalent forms:

The test unit also includes a test sample reagent means, which comprises preselected reagents depending on the desired test to be carried out, and when one or more tests may be carried out alone or in any sequence as desired, with the test reagent means designed to contact the test sample collected. The reagent means generally comprises at least one sealed reagent package containing a test reagent, ***which may be solid, liquid, powder, emulsion, suspension, tablet or substantially any combination separately or admixed thereof.***

Specification, page 6, lines 17-26 (emphasis added).

(b) Attorney Argument. In a non-final Office Action dated November 22, 1999, the rejected the claims over two prior art references. Claims 51, 57-59 and 63¹ were rejected under 102(a) as anticipated by Matsumoto et al. (JP 07-59555) (hereafter "Matsumoto"). In addition, claims 51, 53, 55, 57-59, and 63-65² were rejected under 102(b) as anticipated by Bernstein (US 4,770,853) (hereafter "Bernstein"). Claims 53, 54, 56, 66 and 67³ were further rejected under 103(a) as unpatentable over Bernstein.

Responding to the office action, Mr. Crowley amended certain claims and explained his amendments in attorney argument. As discussed below, the 'tablet' limitation was not one of the patentable distinctions relied on by Mr. Crowley to overcome the art. To the contrary, Mr. Crowley stated on the record that he believed the primary reference, the Matsumoto reference, to disclose a tablet itself.

Discussing Matsumoto, Mr. Crowley argued, first, that the Matsumoto apparatus was not directed to the detection of ATP or AP in a luminescent or color method within the test unit; second, that Matsumoto did not have or suggest single or multiple, separate, aligned unit dose reagent chambers in a test unit; and, third, that Matsumoto did not have a transparent test (micro) unit with a threaded top with a reagent chamber to be removedly secured from one end of the test unit for separate insertion into a photometer for observation. None of Mr. Crowley's remarks indicated that the term 'tablet' was relied on to distinguish over Matsumoto. *See, Amendment, April 17, 2000.*

¹ Application claims 51, 57-59 and 63 matured into claims 1, 5-7, and 14, respectively, of the original patent. *See, Appendix A.*

² Application claims 51, 53, 57-59 and 63-64 matured into claims 1, 3, 5-7, and 14-15, respectively, of the original patent. Application claims 55 and 65 were cancelled. *See, Appendix A.*

³ Application claims 53, 56, and 66 matured into claims 3, 4, and 16, respectively, of the original patent. Application claims 54 and 67 were cancelled. *See, Appendix A*

Mr. Crowley did not stop there. He went on to express his belief that the Matsumoto reference affirmatively *disclosed a tablet*:

The claims have been rejected under Sections 102 and 103 over a newly cited reference, Matsumoto et al, Japanese Patent Application No. 07-59555, and the previously-cited Bernstein U.S. Patent No. 4,770,853. It is respectfully submitted that the claims as amended are allowable over either reference, alone or in combination.

For the convenience of the Examiner and for the record, the Applicants enclose an English-language translation of the Japanese reference (Matsumoto et al Japanese Patent No. 407059555A) together with a Declaration for Translation Under 37 C.F.R. 1.647 by the Translator.

Matsumoto et al is not directed to a separate sealed reagent chamber or to the use of multiple, aligned reagent chambers in a test unit. The Matsumoto et al container is a pocket-type, microbial incubator, not a reagent test apparatus. The Matsumoto et al container provides for the separation of a "liquid substance containing an indicator" in a sealed package, from a dry, inactive microorganism tablet in the bottom end of the incubator. The Matsumoto et al incubator solves the problem of keeping the dry microorganism apart from the liquid until the collecting bead with the sample is used to inoculate the moistened microorganisms.

The Matsumoto et al apparatus is not directed to the detection of ATP or AP in a luminescent or color method within the test unit and does not have or suggest single or multiple, separate, aligned unit dose reagent chambers in a test unit, nor does it have a transparent test (micro) unit with a threaded top, with a reagent chamber to be removedly secured from one end of the test unit for separate insertion into a photometer for observation (see application Figs. 5 and 7).

Amendment, April 17, 2000, pages 5-6 (underlined emphasis in original; italics added).

Turning to the Bernstein reference, Mr. Crowley argued that Bernstein was directed to a solid phase diffusion assay with the test carried out by a membrane over a hole at the bottom end, and, like Matsumoto, was not directed "to the detection of ATP or AP by detection within a test unit." Mr. Crowley explained that,

The Bernstein U.S. Patent No. 4,770,853 is directed to a solid phase diffusion assay with the test carried out by a membrane over a hole at the bottom end, and like the Matsumoto et al patent, it is not directed to the detection of ATP or AP by detection within a test unit. It does not use or suggest separate unit dose reagent chambers, and it does not have, require, or suggest a threaded top to the transparent test unit for insertion of the test unit into a photometer.

Amendment, April 17, 2000, page 6 (emphasis in original).

(c) Changes to the Claims. Mr. Crowley then went on to fully explain his changes to the claims:

Applicants have amended the claims to distinguish clearly over the structure composition and operational features of the cited references, and have directed the reagent chamber, the test unit, and the test apparatus to the detection of ATP or AP.

Applicants have specified in the claims that the dose reagent chamber comprises one of three compositions used in the test detection of ATP or AP and have supported the same in the examples cited in the specification. Applicants have employed "consisting essentially of" to describe such compositions and to exclude additional ingredients which materially affect the basic characteristics of the claimed composition.

Applicants have cancelled certain claims and added dependent claims directed to particular preferred ATP or AP embodiments. Neither Matsumoto et al, nor Bernstein, nor the other references suggest Applicants' separate dose reagent chambers with the recited reagent compositions for ATP or AP tests, nor a test unit with one or more chambers with a threaded top for attachment to an ATP or AP test apparatus, nor to the ATP or AP test apparatus with the combination of separate unit dose chambers in a threaded test unit on one end of a test apparatus.

Amendment, April 17, 2000, pages 6-7. Accordingly, Mr. Crowley added "adenosine triphosphate (ATP) or alkaline phosphatase (AP)" to the preambles of claims 51 and 63, and limited the reagent composition to one of three members of a Markush group:

- i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing;
- ii) a reaction stopping solution having a pH of 8 to 11; and
- iii) a luciferin-luciferase or phosphatase substrate reagent tablet.

But in doing the latter, Mr. Crowley erred by including the term 'tablet' within the amended claim language. By adding the term 'tablet' to the claims, Mr. Crowley erred by claiming less than the Applicants had a right to claim in the patent. It was never Applicants' intent to disclaim the remaining forms of reagent composition disclosed in the specification.⁴

II. Discussion

⁴ Mr. Crowley died on February 13, 2001, two weeks after the January 30, 2001, issue date of the original patent, without having corrected his mistake.

The two-part test articulated by the Court of Appeals for the Federal Circuit (“Federal Circuit”) for applying the recapture rule mandates a review of the intrinsic record for admissions and attorney argument made during prosecution. *See, Hester Industries Inc. v. Stein Inc.*, 46 USPQ2d 1641, 1649 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997). The first part of that test, determining whether and in what aspect the reissue claims are broader than the patent claims, is not in dispute here. Reissue claims 1, 10, 14, 19, and 21 are broadened versions of the corresponding patent claims in that the language “tablet” and “form of tablet” has been replaced with the language “reagent composition.” *See, Office Action*, August 14, 2002 (paper no. 6), page 4.

The second part of the test, determining whether the broader aspects of the reissue claims relate to deliberately surrendered subject matter, requires examining the intrinsic record for admissions, arguments, and changes to the claims that were made in an effort to distinguish over the prior art. *Clement*, 45 USPQ2d at 1164; *Danby*, 58 USPQ2d at 1096 (‘in parallel planes’ limitation was not necessary to secure allowance, and thus not regarded as surrendered subject matter). Although the recapture rule is similar to the doctrine of prosecution history estoppel, it differs in its element of error. *Hester*, 46 USPQ2d at 1649, 1649-50 (“The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects”); *Ball Corp. v. U. S.*, 729 F.2d 1429, 221 USPQ 289, 296 (Fed. Cir. 1984).

The reissue procedure is, after all, an equitable mechanism for correcting error, and thus does not have the rigidity of a complete bar. *Ball*, 221 USPQ at 296 (“The recapture rule, however, is based on equitable principles. The rigidity of the broader-in-any-respect rule makes it

inappropriate in the estoppel situation presented in this appeal.”). In keeping with its equitable nature, the recapture rule is not to be applied in a rigid, ‘broader in any aspect’ manner unless there is insufficient evidence to infer that the reason for a claim amendment was made in error. *Id.* Only when other reliable evidence of the patentee’s intent is not available is improper recapture inferred merely from changes in claim scope. *Id.*, at 294. That is not the case here.

To the extent that having added the ‘tablet’ limitation could be considered a surrender of subject matter, the surrender was not deliberate. It is because the recapture rule is designed to avoid recapture of only that subject matter *deliberately* surrendered during original prosecution that the recapture rule is rooted in the error requirement. *See, Danby*, 58 USPQ2d at 1096 (‘s rejection reversed where reissue claims broader than original claims by deleting limitation “parallel plates”, and where interview summary record indicated that limitation was not necessary).

Dispositive evidence that surrender of subject matter was not deliberately intended is found in the prosecution record. *See, Hester*, 46 USPQ2d 1650; *Eggert*, slip op. at 25, 26, 29. In *Eggert*, the Board declined to apply the recapture rule. Although the omitted limitations ‘permanent, cylindrical,’ and ‘non-circular’ broadened the reissue claims relative to surrendered subject matter, the limitations had not been argued by the appellants during original prosecution to be distinguishing over the prior art. Furthermore, the Board stressed that the same limitations had been met by the primary prior art reference itself, and thus found that such claims were broader only in aspects unrelated to the prior art rejection at issue. *Id.*; compare, *Pannu v. Storz Instruments, Inc.*, 59 USPQ2d 1597 (Fed. Cir. 2001)(recapture rule applied where omitted limitation related to the shape of the haptics, which was *the same characteristic* argued to have been added to distinguish over the prior art).

Furthermore, arguments made during prosecution demonstrate that the 'tablet' limitation was not added to distinguish over the prior art. The arguments put forth by the prosecuting attorney affirmatively identify the distinctions used to overcome the prior art. Attorney argument, in the Amendment of April 17, 2000, addressed the 'type of' reagent composition, not its form. Contrast the explicit nature of these remarks with the fact that the record makes no mention of the additional 'tablet' limitation. Nothing in the Applicants' explanation or in any other part of the prosecution history indicates that either the Examiner or the Applicants considered the 'tablet' limitation necessary to overcome the prior art. *See, In re Willingham*, 282 F.2d 353, 127 USPQ 211, (CCPA 1960) (no intent to surrender where the Applicant canceled and replaced a claim without an intervening action by the Examiner).

The Examiner's reference to MPEP §1412.02, example B, does not apply to the present case. Example B refers to those cases in which no argument accompanies an amendment, so that the record is silent as to what aspect of the amendment was necessary in order to overcome the prior art. That is not the case here. Here, attorney argument clearly articulates the scope of subject matter being surrendered to overcome the prior art, and further demonstrates the attorney's subjective belief that the prior art reference itself met the omitted limitation.

Applicant admissions are further reliable evidence that surrender of subject matter was not intended. Here, the intrinsic record creates a reasonable inference that the prosecuting attorney did not consider the true scope of the invention when adding the 'tablet' limitation. Applicants had disclosed in their specification that the test reagent could be any one of several equivalent forms, including a "solid, liquid, powder, emulsion, suspension, tablet or substantially any combination separately or admixed thereof." *Specification*, page 6, lines 17-26. It follows that

the 'tablet' limitation could not have been considered material for the purpose of distinguishing over other forms of reagent met by the prior art. *See, Hester*, at 1650 (distinguishing material from non-material limitations); *Eggert*, slip op. at 27 (declining to apply the recapture rule where omitted limitations were not material to patentability). The prosecuting attorney would not have intended to disclaim the very same embodiments that the specification disclosed as being equally appropriate for practicing the teachings of the disclosed invention.

Thus, it is impossible that the 'tablet' limitation could have been deliberately surrendered to overcome Matsumoto. The prosecuting attorney points out that Matsumoto et al. discloses a dry tablet at the bottom of Matsumoto's test apparatus. Given that he thought the Matsumoto reference itself disclosed a tablet, he would not have attempted to seek allowance of the claims based on such a limitation.

For all of the above reasons, Applicants submit that the recapture does not apply in the present case, and respectfully request that the rejection under 35 U.S.C. § 251 be withdrawn.

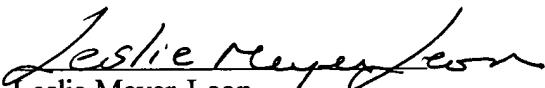
CONCLUSION

The present Amendment is being filed within six months of the mailing date of the Office Action. A Petition for Extension of Time Under 37 C.F.R. 1.136(a) for a three-month extension of time is respectfully submitted herewith. A check in the amount of \$465.00 is enclosed for the extension of time under 37 C.F.R. 1.17(a)(3).

Applicant respectfully submits that the application is in condition for allowance. Please charge any outstanding fees or overpayments to Deposit Account No. 50-1895, Ref. No. 0656-008US6.

Respectfully submitted,

Date: Feb. 14, 2003


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Enclosures: Version with markings to show changes made (3 pgs.)

Petition for Extension of Time
Supplemental Reissue Declaration
Appendices A and B
Exhibits 1 and 2
Check
Postcard

VERSION WITH MARKINGS TO SHOW CHANGES TO THE CLAIMS

3. (Amended) The chamber of claim 1, wherein the reagent composition is a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing, and wherein the reagent composition comprises a phosphoric acid buffer and an anionic or non-ionic detergent.

4. (Amended) The chamber of claim 1, wherein the reagent composition is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; (ii) a reaction stopping solution having a pH of 8 to 11; and (iii) a luciferin-luciferase or phosphatase substrate reagent, and wherein the reagent composition includes a pH indicator.

5. (Amended) In combination, the chamber of claim 1 in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, wherein the reagent composition is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; and (ii) a reaction stopping solution having a pH of 8 to 11, which test apparatus includes a luciferin-luciferase or phosphatase substrate reagent for reaction with the released adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution.

6. (Amended) The combination of claim 5 wherein the test apparatus [includes] further comprises a longitudinally moveable probe to puncture the membrane seals [to carry out the test].

10. (Twice amended) The combination of claim 7, wherein the reagent composition is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution

for testing; and (ii) a reaction stopping solution having a pH of 8 to 11 [wherein the sealed compartment comprises the buffered-detergent solution] and wherein said test apparatus includes a luciferase and a luciferin reagent at the bottom end of the test unit.

11. (Amended) The combination of claim [5]6, wherein the test apparatus [includes] further comprises a threadable means to move the probe spirally and longitudinally to puncture the membrane seals.

12. (Amended) The chamber of claim 1, wherein the reagent composition is selected from the group consisting of i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; ii) a reaction stopping solution having a pH of 8 to 11; and iii) a luciferin-luciferase or phosphatase substrate reagent, and wherein the reagent composition includes a biological buffer solution to optimize a reaction for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP).

21. (Twice Amended) A transparent test unit for use in a test apparatus, [for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP),] and which test unit comprises: a one [open] end; a closed bottom end; a probe-puncturable membrane over the one end; and the one end having threads for [threadable] attachment of the test unit to the test apparatus, and the test unit having one or more [separate, longitudinally-aligned] unit dose reagent chambers, which unit dose chamber comprises:

- a) a cylinder having a one open end and an other opposite open end;
- b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment; and
- c) a reagent composition for use in the detection of [adenosine triphosphate (ATP) or

alkaline phosphatase (AP) in] the test sample and sealed within the sealed compartment[, which comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution; and

d) a reagent composition at the bottom end to detect the adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution].

| Claims as filed (see Preliminary Amendment of 11/27/95) | Claims as amended April 17, 2000 (and as allowed and issued) |
|---|--|
| <p>51. A unit dose reagent chamber for use in a test apparatus for the detection of a test sample, and wherein a moveable probe is employed to obtain a test sample and to release reagents from the reagent chamber to a test unit, which unit dose chamber comprises:</p> <ul style="list-style-type: none"> a) a cylinder having a one open end and an other opposite open end; b) a probe-puncturable membrane seal at and over the one end and the other end of the cylinder to form a sealed compartment; and c) a reagent composition for use in the detection of the test sample and sealed within the sealed compartment. | <p>1[51]. A unit dose reagent chamber for use in a test apparatus for the detection of <u>adenosine triphosphate (ATP)</u> or <u>alkaline phosphatase (AP)</u> in a test sample, and wherein a moveable probe is employed to obtain a test sample and to release reagents from the reagent chamber to a test unit, which unit dose chamber comprises:</p> <ul style="list-style-type: none"> a) a cylinder having a one open end and an other opposite open end; b) a probe-puncturable membrane seal [at and] over the one end and the other end of the cylinder to form a sealed compartment; and c) a reagent composition [means] for use in the detection of the test sample and sealed within the sealed compartment, <u>which composition consists essentially of and is selected from the group consisting of:</u> i) <u>a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing;</u> ii) <u>a reaction stopping solution having a pH of 8 to 11;</u> and iii) <u>a luciferin-luciferase or phosphatase substrate reagent tablet.</u> |
| 52. The chamber of claim 51 wherein the membrane seal comprises aluminum foil. | 2[52]. The chamber of claim 51 wherein the membrane seal comprises aluminum foil. |
| 53. The chamber of claim 51 used for the detection of ATP, and wherein the reagent composition comprises a phosphoric acid and detergent solution. | 3[53]. The chamber of claim 51 [used for the detection of ATP, and] wherein the reagent composition comprises a phosphoric acid buffer and <u>an anionic or non-ionic detergent [solution].</u> |
| 54. The chamber of 51 used for the detection of ATP, and wherein the reagent composition comprises a luciferase and a luciferin substrate reagent tablet. | 54. Cancelled. |
| 55. The chamber of claim 51 wherein the reagent composition is selected from the group consisting of: water; a buffer solution; a neutralizer solution; a dye indicator; an enzyme; luciferin and luciferase; dried microorganisms; nutrients for microorganisms; and combinations thereof. | 55. Cancelled. |
| 56. The chamber of claim 51 wherein the reagent means composition includes a pH indicator. | 4[56]. The chamber of claim 51 wherein the reagent [means] composition includes a pH indicator. |
| 57. In combination, the chamber of claim 51 in a test apparatus for the detection of a test sample. | 5 [57]. In combination, the chamber of claim 51 in a test apparatus for the detection of <u>adenosine triphosphate (ATP)</u> or <u>alkaline phosphatase (AP)</u> in a test sample, <u>which test apparatus includes a luciferin-luciferase or phosphatase substrate reagent for reaction with the released adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution.</u> |

| Claims as filed (see Preliminary Amendment of 11/27/95) | Claims as amended April 17, 2000 (and as allowed and issued) |
|--|--|
| 58. The combination of claim 57 wherein the test apparatus includes a longitudinally moveable probe to puncture the sealed membranes to carry out the test. | 6 [58]. The combination of claim 57 wherein the test apparatus includes a longitudinally moveable probe to puncture the [sealed membranes] <u>membrane seals</u> to carry out the test. |
| 59. The combination of claim 57 wherein the test apparatus includes a transparent test unit at the one end of the test apparatus, and the one or more chambers longitudinally positioned in the test unit. | 7 [59]. The combination of claim 57 wherein the test apparatus includes a <u>closed bottom end</u> , transparent test unit at the one end of the test apparatus, and [the] wherein one or more <u>unit dose reagent</u> chambers <u>are</u> longitudinally positioned in the test unit. |
| 60. The combination of claim 59 wherein the test unit has an open top end and a closed bottom end and is removedly, threadably secured to one end of the test apparatus. | 8 [60]. The combination of claim 59 wherein the test unit has an open top end <u>with threads</u> and a closed bottom end, and <u>the test unit</u> is removedly, threadably secured to one end of the test apparatus. |
| 61. The combination of claim 59 wherein the one end of the test unit is sealed with a probe-puncturable membrane. | 9 [61]. The combination of claim [59] 60 wherein the [one] <u>top</u> end of the test unit is sealed with a probe-puncturable membrane <u>seal</u> . |
| 62. The chamber of claim 59 wherein the sealed compartment comprises the buffer-detergent solution; and a luciferase and a luciferin substrate, in tablet form, is in the bottom end of the test unit. | 10 [62]. The [chamber] <u>combination</u> of claim 59 wherein the sealed compartment comprises [a buffer] <u>the buffered-detergent solution</u> [;] and a luciferase and a luciferin [substrate,] <u>reagent</u> in tablet form[, is in] <u>at</u> the bottom end of the test unit. |
| <p>63. A test apparatus for the detection of a test sample by luminescence or color, which test apparatus comprises:</p> <ul style="list-style-type: none"> a) a longitudinal test apparatus housing having a one end and an other end; b) a moveable probe within the housing to collect a test sample; c) a transparent test unit at the one end of the housing for use in detecting luminescence or color in the test; and d) one or more reagent chambers longitudinally positioned in the test unit, which reagent chamber comprises: <ul style="list-style-type: none"> i) a cylinder having a one open end and an other opposite open end; ii) a probe-puncturable membrane seal at and over the one end and the other end of the cylinder to form a sealed compartment; and iii) a reagent composition means for use in the detection of the test sample and sealed within the sealed compartment. | <p>14 [63]. A test apparatus for the detection of <u>adenosine triphosphate (ATP)</u> or <u>alkaline phosphatase (AP)</u> in a test sample, by luminescence or color, which test apparatus comprises:</p> <ul style="list-style-type: none"> a) a longitudinal test apparatus housing having a one end and an other end; b) a moveable probe within the housing to collect a test sample <u>and arranged to puncture a membrane seal</u>; c) a transparent test unit [at] <u>having a one end and a closed bottom end extending from</u> the one end of the housing for use in detecting luminescence or color in the test sample, <u>and a reagent tablet to detect adenosine triphosphate (ATP)</u> or <u>alkaline phosphatase (AP)</u>, <u>by color or luminescence, at the closed bottom end</u>; and d) one or more <u>unit dose</u> reagent chambers longitudinally-positioned in the test unit, which reagent chamber comprises: <ul style="list-style-type: none"> i) a cylinder having a one open end and an other opposite open end; ii) a probe-puncturable membrane seal at and over the one end and the other end of the cylinder to form a sealed compartment; and iii) a reagent composition [means] for use in the detection of <u>adenosine triphosphate (ATP)</u> or <u>alkaline</u> |

| Claims as filed (see Preliminary Amendment of 11/27/95) | Claims as amended April 17, 2000 (and as allowed and issued) |
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| | <p><u>phosphatase (AP) in the test sample and sealed within the sealed compartment, which reagent composition comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for subsequent reaction with the reagent tablet.</u></p> |
| 64. The apparatus of claim 63 wherein the membrane seal comprises aluminum foil. | 15 [64]. The apparatus of claim 63 wherein the membrane seal comprises aluminum foil. |
| 65. The apparatus of claim 63 wherein the reagent composition is selected from the group consisting of: water; a buffer solution; a neutralizer solution; a dye indicator; an enzyme; luciferin and luciferase; dried microorganisms; nutrients for microorganisms; and combinations thereof. | 65. Cancelled. |
| 66. The apparatus of claim 63 used for the detection of ATP, and wherein the reagent composition comprises a phosphoric acid and a detergent solution. | 16 [66]. The apparatus of claim 63 [used for the detection of ATP, and] wherein the reagent composition comprises a phosphoric acid and a detergent solution. |
| 67. The apparatus of claim 63 used for the detection of ATP, and wherein the reagent composition comprises a luciferase and a luciferin substrate reagent tablet. | 67. Cancelled. |
| 68. The apparatus of claim 63 wherein the test unit has an open top end and a closed bottom end and is removably, threadably secured to one end of the test apparatus. | 17 [68]. The apparatus of claim 63 wherein the test unit has an open top end with threads, and a closed bottom end and is removably, threadably secured to one end of the test apparatus. |

| Claims as filed (see Preliminary Amendment of 11/27/95) | Claims as amended April 17, 2000 (and as allowed and issued) |
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| 69. The apparatus of claim 63 wherein the one end of the test unit is sealed with a probe-puncturable membrane. | 18 [69]. The apparatus of claim 63 wherein the one end of the test unit is sealed with a probe-puncturable membrane. |
| 70. The apparatus of claim 63 wherein the sealed compartment comprises a buffer-detergent solution and a luciferase and a luciferin substrate, in tablet form, is in the bottom end of the test unit. | 19 [70]. The apparatus of claim 63 wherein the sealed compartment comprises a buffer-detergent solution and a luciferase and a luciferin substrate, [in] as a <u>reagent</u> tablet [form], is [in] at the bottom end of the test unit. |
| 71. The apparatus of claim 63 which includes two sequential reagent chambers comprising: a first chamber containing a reagent solution to release phosphatase from the probe; and a second chamber containing a reagent for the luminescent detection of the phosphatase in the test unit. | 20 [71]. The apparatus of claim 63 which includes two sequential reagent <u>unit dose</u> chambers comprising: a first chamber containing [a] <u>the</u> reagent solution to release phosphatase from the probe; and a second chamber containing a reagent for the [luminescent] detection of the phosphatase in the test [unit] <u>sample</u> . |
| 72. The apparatus of claim 66 which includes three sequential chambers, and which chambers comprise: a first chamber of a solution; a second chamber of dried luminescent bacteria; and a third chamber of an enhancing solution. | 72. Cancelled. |
| 73. A transparent test unit for use in a test apparatus, and which test unit comprises: a one end; a closed bottom end; a probe-puncturable membrane over the one end; and the one end having threads for attachment of the test unit to the test apparatus, and the test unit having one or more unit dose reagent chambers of claim 51 therein. | 21 [73]. A transparent test unit for use in a test apparatus, <u>for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP)</u> , and which test unit comprises: a one <u>open</u> end; a closed bottom end; a probe-puncturable membrane over the one end; and the one end having threads for <u>threadable</u> attachment of the test unit to the test apparatus, and the test unit having one or more <u>separate, longitudinally-aligned</u> unit dose reagent chambers [of claim 51 therein], <u>which unit dose chamber comprises</u> : a) <u>a cylinder having a one open end and an other opposite open end</u> ; b) <u>a probe-puncturable membrane seal [at and] over the one end and the other end of the cylinder to form a sealed compartment</u> ; c) <u>a reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution; and</u> d) <u>a reagent tablet at the bottom end to detect the adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution</u> . |
| 74. The test unit of claim 73 wherein the probe-puncturable membrane comprises aluminum foil. | 22 [74]. The test unit of claim 73 wherein the probe-puncturable membrane seal comprises aluminum foil. |

| Claims as filed (see Preliminary Amendment of 11/27/95) | Claims as amended April 17, 2000 (and as allowed and issued) |
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| 75. The test unit of claim 73 wherein at least one of the reagent chambers contain a reagent solution, and the test unit includes a reagent in tablet form. | 23 [75]. The test unit of claim 73 wherein [at least one of the reagent chambers contain a reagent solution, and] the test unit includes a <u>luciferin-luciferase</u> reagent [in] tablet [form]. |
| | 12 [76]. The chamber of claim 51 wherein the reagent composition includes a biological buffer solution to optimize a reaction for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP). |
| | 13 [77]. The chamber of claim 76 wherein the biological buffer comprises tris(hydroxymethyl)aminomethane (TRIS) or tricine. |
| | 11 [78]. The combination of claim 57 wherein the test apparatus includes a threadable means to move the probe spirally and longitudinally to puncture the membrane seals. |

| Original Patent Claim | Reissue Claims, as filed Dec. 6, 2001 | Reissue Claims (after entry of present amendment) |
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| <p>1 [51]. A unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, and wherein a moveable probe is employed to obtain a test sample and to release reagents from the reagent chamber to a test unit, which unit dose chamber comprises:</p> <p>a) a cylinder having a one open end and an other opposite open end;</p> <p>b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment; and</p> <p>c) a reagent composition for use in the detection of the test sample and sealed within the sealed compartment, which composition consists essentially of and is selected from the group consisting of:</p> <p>i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing;</p> <p>ii) a reaction stopping solution having a pH of 8 to 11; and</p> <p>iii) a luciferin-luciferase or phosphatase substrate reagent tablet.</p> | <p>1. (Amended) A unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, and wherein a moveable probe is employed to obtain a test sample and to release reagents from the reagent chamber to a test unit, which unit dose chamber comprises:</p> <p>a) a cylinder having a one open end and an other opposite open end;</p> <p>b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment; and</p> <p>c) a reagent composition [for use in the detection of the test sample and sealed] within the sealed compartment, which composition consists essentially of and is selected from the group consisting of:</p> <p>i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing;</p> <p>ii) a reaction stopping solution having a pH of 8 to 11; and</p> <p>iii) a luciferin-luciferase or phosphatase substrate reagent [tablet].</p> | <p>1. A unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, and wherein a moveable probe is employed to obtain a test sample and to release reagents from the reagent chamber to a test unit, which unit dose chamber comprises:</p> <p>a) a cylinder having a one open end and an other opposite open end;</p> <p>b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment; and</p> <p>c) a reagent composition within the sealed compartment, which composition consists essentially of and is selected from the group consisting of:</p> <p>i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing;</p> <p>ii) a reaction stopping solution having a pH of 8 to 11; and</p> <p>iii) a luciferin-luciferase or phosphatase substrate reagent.</p> |
| <p>2 [52]. The chamber of claim 1[51] wherein the membrane seal comprises aluminum foil.</p> | <p>2. The chamber of claim 1 wherein the membrane seal comprises aluminum foil.</p> | <p>2. The chamber of claim 1 wherein the membrane seal comprises aluminum foil.</p> |
| <p>3 [53]. The chamber of claim 1[51] wherein the reagent composition comprises a phosphoric acid buffer and an anionic or non-ionic detergent.</p> | <p>3. The chamber of claim 1 wherein the reagent composition comprises a phosphoric acid buffer and an anionic or non-ionic detergent.</p> | <p>3. (Amended) The chamber of claim 1, wherein the reagent composition is a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing, and wherein the reagent composition comprises a phosphoric acid buffer and an anionic or non-ionic detergent.</p> |
| <p>4 [56]. The chamber of claim 1[51] wherein the reagent composition includes a pH indicator.</p> | <p>4. The chamber of claim 1 wherein the reagent composition includes a pH indicator.</p> | <p>4. (Amended) The chamber of claim 1, wherein the reagent composition is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing;</p> |

| Original Patent Claim | Reissue Claims, as filed Dec. 6, 2001 | Reissue Claims (after entry of present amendment) |
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| | | and (ii) a reaction stopping solution having a pH of 8 to 11 and (iii) a luciferin-luciferase or phosphatase substrate reagent, and wherein the reagent composition includes a pH indicator. |
| 5 [57]. In combination, the chamber of claim 1[51] in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, which test apparatus includes a luciferin-luciferase or phosphatase substrate reagent for reaction with the released adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution. | 5. In combination, the chamber of claim 1 in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, which test apparatus includes a luciferin-luciferase or phosphatase substrate reagent for reaction with the released adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution. | 5. (Amended) In combination, the chamber of claim 1 in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, wherein the reagent composition is selected from the group consisting of (i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; and (ii) a reaction stopping solution having a pH of 8 to 11, which test apparatus includes a luciferin-luciferase or phosphatase substrate reagent for reaction with the released adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution. |
| 6 [58]. The combination of claim 5[57] wherein the test apparatus includes a longitudinally moveable probe to puncture the membrane seals to carry out the test. | 6. The combination of claim 5 wherein the test apparatus includes a longitudinally moveable probe to puncture the membrane seals to carry out the test. | 6. (Amended) The combination of claim 5 wherein the test apparatus [includes] further comprises a longitudinally moveable probe to puncture the membrane seals [to carry out the test]. |
| 7 [59]. The combination of claim 5[57] wherein the test apparatus includes a closed bottom end, transparent test unit at the one end of the test apparatus, and wherein one or more unit dose reagent chambers are longitudinally positioned in the test unit. | 7. The combination of claim 5 wherein the test apparatus includes a closed bottom end, transparent test unit at the one end of the test apparatus, and wherein one or more unit dose reagent chambers are longitudinally positioned in the test unit. | 7. The combination of claim 5 wherein the test apparatus includes a closed bottom end, transparent test unit at the one end of the test apparatus, and wherein one or more unit dose reagent chambers are longitudinally positioned in the test unit. |
| 8 [60]. The combination of claim 7[59] wherein the test unit has an open top end with threads and a closed bottom end, and the test unit is removedly, threadably secured to one end of the test apparatus. | 8. The combination of claim 7 wherein the test unit has an open top end with threads and a closed bottom end, and the test unit is removedly, threadably secured to one end of the test apparatus. | 8. The combination of claim 7 wherein the test unit has an open top end with threads and a closed bottom end, and the test unit is removedly, threadably secured to one end of the test apparatus. |
| 9 [61]. The combination of claim 8[60] wherein the top end of the test unit is sealed with a probe-puncturable membrane seal. | 9. The combination of claim 8 wherein the top end of the test unit is sealed with a probe-puncturable membrane seal. | 9. The combination of claim 8 wherein the top end of the test unit is sealed with a probe-puncturable membrane seal. |

| Original Patent Claim | Reissue Claims, as filed Dec. 6, 2001 | Reissue Claims (after entry of present amendment) |
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| 10 [62].The combination of claim 7[59] wherein the sealed compartment comprises the buffered-detergent solution and a luciferase and a luciferin reagent in tablet form at the bottom end of the test unit. | 10. (Amended) The combination of claim 7 wherein the sealed compartment comprises the buffered-detergent solution and a luciferase and a luciferin reagent [in tablet form] at the bottom end of the test unit. | 10. (Twice Amended) The combination of claim 7, <u>wherein the reagent composition is selected from the group consisting of (I) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; and (ii) a reaction stopping solution having a pH of 8 to 11</u> [wherein the sealed compartment comprises the buffered-detergent solution] and <u>wherein said test apparatus includes</u> a luciferase and a luciferin reagent at the bottom end of the test unit. |
| 11 [78].The combination of claim 5[57] wherein the test apparatus includes a threadable means to move the probe spirally and longitudinally to puncture the membrane seals. | 11.The combination of claim 5 wherein the test apparatus includes a threadable means to move the probe spirally and longitudinally to puncture the membrane seals. | 11. (Amended) The combination of claim [5]6, wherein the test apparatus [includes] <u>further comprises</u> a threadable means to move the probe spirally and longitudinally to puncture the membrane seals. |
| 12 [76].The chamber of claim 1[51] wherein the reagent composition includes a biological buffer solution to optimize a reaction for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP). | 12.The chamber of claim 1 wherein the reagent composition includes a biological buffer solution to optimize a reaction for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP). | 12. (Amended) The chamber of claim 1, <u>wherein the reagent composition is selected from the group consisting of i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing; ii) a reaction stopping solution having a pH of 8 to 11; and iii) a luciferin-luciferase or phosphatase substrate reagent</u> , and <u>wherein the reagent composition includes a biological buffer solution to optimize a reaction for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP)</u> . |
| 13 [77].The chamber of claim 12[76] wherein the biological buffer comprises tris(hydroxymethyl)aminomethane (TRIS) or tricine. | 13.The chamber of claim 12 wherein the biological buffer comprises tris(hydroxymethyl)aminomethane (TRIS) or tricine. | 13.The chamber of claim 12 wherein the biological buffer comprises tris(hydroxymethyl)aminomethane (TRIS) or tricine. |
| 14 [63].A test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, by luminescence or color, which test apparatus comprises a) a longitudinal test apparatus housing having a one end and an other end; | 14. (Amended) A test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, by luminescence or color, which test apparatus comprises a) a longitudinal test apparatus housing having a one end and an other | 14. A test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, by luminescence or color, which test apparatus comprises a) a longitudinal test apparatus housing having a one end and an other |

| Original Patent Claim | Reissue Claims, as filed Dec. 6, 2001 | Reissue Claims (after entry of present amendment) |
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| <p>b) a moveable probe within the housing to collect a test sample and arranged to puncture a membrane seal;</p> <p>c) a transparent test unit having a one end and a closed bottom end extending from the one end of the housing for use in detecting luminescence or color in the test sample, and a reagent tablet to detect adenosine triphosphate (ATP) or alkaline phosphatase (AP), by color or luminescence, at the closed bottom end; and</p> <p>d) one or more unit dose reagent chambers longitudinally-positioned in the test unit, which reagent chamber comprises:</p> <ul style="list-style-type: none"> i) a cylinder having a one open end and an other opposite open end; ii) a probe-puncturable membrane seal at and over the one end and the other end of the cylinder to form a sealed compartment; and iii) a reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which reagent composition comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for subsequent reaction with the reagent tablet. | <p>end;</p> <p>b) a moveable probe within the housing to collect a test sample and arranged to puncture a membrane seal;</p> <p>c) a transparent test unit having a one end and a closed bottom end extending from the one end of the housing for use in detecting luminescence or color in the test sample, and a <u>first</u> reagent [tablet] <u>composition</u> to detect adenosine triphosphate (ATP) or alkaline phosphatase (AP), by color or luminescence, at the closed bottom end; and</p> <p>d) one or more unit dose reagent chambers longitudinally-positioned in the test unit, which reagent chamber comprises:</p> <ul style="list-style-type: none"> i) a cylinder having a one open end and an other opposite open end; ii) a probe-puncturable membrane seal at and over the one end and the other end of the cylinder to form a sealed compartment; and iii) a <u>second</u> reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which reagent composition comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for subsequent reaction with the <u>first</u> reagent [tablet]composition. | <p>end;</p> <p>b) a moveable probe within the housing to collect a test sample and arranged to puncture a membrane seal;</p> <p>c) a transparent test unit having a one end and a closed bottom end extending from the one end of the housing for use in detecting luminescence or color in the test sample, and a <u>first</u> reagent composition to detect adenosine triphosphate (ATP) or alkaline phosphatase (AP), by color or luminescence, at the closed bottom end; and</p> <p>d) one or more unit dose reagent chambers longitudinally-positioned in the test unit, which reagent chamber comprises:</p> <ul style="list-style-type: none"> i) a cylinder having a one open end and an other opposite open end; ii) a probe-puncturable membrane seal at and over the one end and the other end of the cylinder to form a sealed compartment; and iii) a <u>second</u> reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which reagent composition comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for subsequent reaction with the <u>first</u> reagent composition. |
| 15 [64].The apparatus of claim 14[63] wherein the membrane seal comprises aluminum foil. | 15.The apparatus of claim 14 wherein the membrane seal comprises aluminum foil. | 15.The apparatus of claim 14 wherein the membrane seal comprises aluminum foil. |
| 16 [66].The apparatus of claim 14[63] wherein the reagent composition comprises a phosphoric acid and a detergent solution. | 16. (Amended) The apparatus of claim 14 wherein the <u>second</u> reagent composition comprises a phosphoric acid and a detergent solution. | 16.The apparatus of claim 14 wherein the second reagent composition comprises a phosphoric acid and a detergent solution. |
| 17[68].The apparatus of claim 14[63] wherein the test unit has an open top end with threads, and a closed bottom end and is removedly, threadably secured to one end of the test apparatus. | 17.The apparatus of claim 14 wherein the test unit has an open top end with threads, and a closed bottom end and is removedly, threadably secured to one end of the test apparatus. | 17.The apparatus of claim 14 wherein the test unit has an open top end with threads, and a closed bottom end and is removedly, threadably secured to one end of the test apparatus. |

| Original Patent Claim | Reissue Claims, as filed Dec. 6, 2001 | Reissue Claims (after entry of present amendment) |
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| 18 [69]. The apparatus of claim 14[63] wherein the one end of the test unit is sealed with a probe-puncturable membrane. | 18. The apparatus of claim 14 wherein the one end of the test unit is sealed with a probe-puncturable membrane. | 18. The apparatus of claim 14 wherein the one end of the test unit is sealed with a probe-puncturable membrane. |
| 19 [70]. The apparatus of claim 14[63] wherein the sealed compartment comprises a buffer-detergent solution and a luciferase and a luciferin substrate, as a reagent tablet, is at the bottom end of the test unit. | 19.(Amended) The apparatus of claim 14 wherein the sealed compartment comprises a buffer-detergent solution and a luciferase and a luciferin substrate, as a reagent [tablet,] is at the bottom end of the test unit. | 19.The apparatus of claim 14 wherein the sealed compartment comprises a buffer-detergent solution and a luciferase and a luciferin substrate, as a reagent is at the bottom end of the test unit. |
| 20 [71]. The apparatus of claim 14[63] which includes two sequential reagent unit dose chambers comprising: a first chamber containing the reagent solution to release phosphatase from the probe; and a second chamber containing a reagent for the detection of the phosphatase in the test sample. | 20.The apparatus of claim 14 which includes two sequential reagent unit dose chambers comprising: a first chamber containing the reagent solution to release phosphatase from the probe; and a second chamber containing a reagent for the detection of the phosphatase in the test sample. | 20.The apparatus of claim 14 which includes two sequential reagent unit dose chambers comprising: a first chamber containing the reagent solution to release phosphatase from the probe; and a second chamber containing a reagent for the detection of the phosphatase in the test sample. |

| Original Patent Claim | Reissue Claims, as filed Dec. 6, 2001 | Reissue Claims (after entry of present amendment) |
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| <p>21 [73].A transparent test unit for use in a test apparatus, for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP), and which test unit comprises: a one open end; a closed bottom end; a probe-puncturable membrane over the one end; and the one end having threads for threadable attachment of the test unit to the test apparatus, and the test unit having one or more separate, longitudinally-aligned unit dose reagent chambers, which unit dose chamber comprises:</p> <p>a) a cylinder having a one open end and an other opposite open end;</p> <p>b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment;</p> <p>c) a reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which comprises a solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution; and</p> <p>d) a reagent tablet at the bottom end to detect the adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution.</p> | <p>21. A transparent test unit for use in a test apparatus, for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP), and which test unit comprises: a one open end; a closed bottom end; a probe-puncturable membrane over the one end; and the one end having threads for threadable attachment of the test unit to the test apparatus, and the test unit having one or more separate, longitudinally-aligned unit dose reagent chambers, which unit dose chamber comprises:</p> <p>a) a cylinder having a one open end and an other opposite open end;</p> <p>b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment;</p> <p>c) a reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which comprises a solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution; and</p> <p>d) a reagent <u>composition</u> [tablet] at the bottom end to detect the adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution.</p> | <p>21. (Twice Amended) A transparent test unit for use in a test apparatus, [for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP),] and which test unit comprises: a one [open] end; a closed bottom end; a probe-puncturable membrane over the one end; and the one end having threads for [threadable] attachment of the test unit to the test apparatus, and the test unit having one or more [separate, longitudinally-aligned] unit dose reagent chambers, which unit dose chamber comprises:</p> <p>a) a cylinder having a one open end and an other opposite open end;</p> <p>b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment; and</p> <p>c) a reagent composition for use in the detection of [adenosine triphosphate (ATP) or alkaline phosphatase (AP) in] the test sample and sealed within the sealed compartment[, which comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution; and</p> <p>d) a reagent composition at the bottom end to detect the adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution].</p> |
| <p>22 [74].The test unit of claim 21[73] wherein the probe-puncturable membrane seal comprises aluminum foil.</p> | <p>22. The test unit of claim 21 wherein the probe-puncturable membrane seal comprises aluminum foil.</p> | <p>22. The test unit of claim 21 wherein the probe-puncturable membrane seal comprises aluminum foil.</p> |
| <p>23 [75].The test unit of claim 21[73] wherein the test unit includes a luciferin-luciferase reagent tablet.</p> | <p>23. The test unit of claim 21 wherein the test unit includes a luciferin-luciferase reagent [tablet].</p> | <p>23. The test unit of claim 21 wherein the test unit includes a luciferin-luciferase reagent.</p> |
| | <p>24 (New). The apparatus of claim 14, wherein said luciferase and said luciferin reagent are in tablet form.</p> | <p>24. The apparatus of claim 14, wherein said luciferase and said luciferin reagent are in tablet form.</p> |
| | <p>25 (New). The test unit of claim 21, wherein said reagent composition is in tablet form.</p> | <p>25. The test unit of claim 21, wherein said reagent composition is in tablet form.</p> |
| | <p>26 (New). The test unit of claim 23, wherein said luciferin-luciferase reagent is a</p> | <p>26. The test unit of claim 23, wherein said luciferin-luciferase reagent is a</p> |

| Original Patent Claim | Reissue Claims, as filed Dec. 6, 2001 | Reissue Claims (after entry of present amendment) |
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| | a luciferin-luciferase tablet. | luciferin-luciferase tablet. |

yer, No. 98 Civ. 5519, 1999 WL 528181, at *10 (S.D.N.Y. July 22, 1999); *ABF Capital Management v. Askin Capital Management, L.P.*, 957 F.Supp. 1308, 1325 (S.D.N.Y. 1997).

C. Plaintiff's Renewal Term State Law Claims

Resolution of defendants' statute of limitations defenses to plaintiff's state law claims also is inappropriate on a motion to dismiss for the reasons discussed in the copyright context. Defendants also contend, however, that Swan's claim for unjust enrichment is preempted by the Copyright Act, and should therefore be dismissed, and that Swan's claim for breach of fiduciary duty should be dismissed for failure to allege a fiduciary relationship.

1. Unjust Enrichment

"The Copyright Act preempts a state cause of action if the subject matter of the state law right falls within the subject matter of federal copyright law and the state law rights are equivalent to the rights federal copyright law protects." *Netzer*, 963 F.Supp. at 1321; *see also Boyle v. Stevens*, No. 97 CIV. 1351, 1998 WL 690816, at *4 (S.D.N.Y. Sept. 29, 1998). In determining whether a state law creates rights that are equivalent to those provided by federal copyright law, a Court must determine whether the state cause of action requires an "extra element" in addition to or instead of the acts of "reproduction, performance, distribution or display" required by the Copyright Act. *Computer Assoc. Int'l, Inc. v. Altai, Inc.*, 982 F.2d 693, 716 [23 USPQ2d 1241] (2d Cir. 1992).

Here, the unjust enrichment claim arises from the same circumstances and seeks vindication of the same rights as plaintiff's claims pursuant to copyright law. That claim is therefore dismissed.

2. Breach of Fiduciary Duty

No fiduciary relationship exists between a music publisher and a composer as a matter of law, unless "special circumstances" are found to exist giving rise to such a relationship. *Carter v. Goodman Group Music Publishers*, 848 F.Supp. 438, 445 (S.D.N.Y. 1994). As currently pled, plaintiff's claim for breach of fiduciary duties is devoid of any "special circumstances" establishing the existence of a fiduciary duty.

Swan seeks leave to replead this claim on the basis that the former owner of defendant

LLEE Music Corp., Lee V. Eastman, was also the personal attorney for Stillman and that this relationship constitutes one of the "special circumstances" giving rise to a fiduciary relationship. Plaintiff will be given leave to re-plead this claim.

III. CONCLUSION

For the reasons set forth above, defendants' motion to dismiss is: (1) granted with prejudice as to plaintiff's claim for royalties for any time period covered by the 1960 Registration or the Amended Registration; (2) granted with prejudice as to plaintiff's sixth claim (for unjust enrichment); (3) granted without prejudice to plaintiff serving an amended complaint within 20 days as to plaintiff's fifth claim (for breach of fiduciary duty); and (4) in all other respects denied.

SO ORDERED.

Ex parte Danby

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

No. 1998-2911

Decided July 7, 2000

Released December 20, 2000

(Unpublished)

PATENTS

[1] Practice and procedure in Patent and Trademark Office — Reissue — Broader claims sought (§ 110.1313)

Absence of "in parallel planes" language from reissue claims of patent for pumping device for supplying intravenous fluids to medical patients does not pose recapture problem that warrants rejection of claims under 35 U.S.C. § 251, since summary of interview conducted prior to addition of "in parallel planes" limitation to original claims makes no mention of that limitation, since applicants subsequently added limitation with explanation that it was consistent with fact that invention deforms tubing, in order to restrict flow of liquid therethrough, over surface area defined by parallel planes rather than single plane, since there is nothing in applicants' ex-

planation or in any other part of prosecution history which indicates that either examiner or applicants considered this limitation necessary to overcome prior art, and since "in parallel planes" language therefore does not relate to surrendered subject matter.

Particular patents — General and mechanical — Intravenous fluid pump

5,151,019, Danby and Faulkner, pumping device having inlet and outlet valves adjacent opposed sides of a tube deforming device, rejection of claims 35 and 36 in reissue application reversed.

Application of Hal C. Danby and Eric A. Faulkner for reissue of patent, serial no. 08/314,345.¹ Applicants appeal from final rejection of claims 35 and 36 in reissue application. Reversed.

[Editor's Note: The Board of Patent Appeals and Interferences states that this decision is not binding precedent of the board.]

Francis C. Kowalik, of Baxter International Inc., Deerfield, Ill.; Paul E. Schaafsma, of Foley & Lardner, Chicago, Ill., for applicants.

Before Cohen, Frankfort, and McQuade, administrative patent judges.

McQuade, J.

DECISION ON APPEAL

Hal C. Danby et al. appeal from the final rejection of claims 35 and 36. Claims 1 through 34, the only other claims pending in the application, stand allowed.

THE INVENTION

The invention relates to a pumping device for supplying intravenous fluids to a medical patient. In general, the device includes means for accommodating a length of tubing, means for deforming the tubing to reduce its volume and valve means adjacent opposed sides of the deforming means for restricting the flow of liquid through the tubing. A copy of claims 35 and 36 appears in the appendix to the appellants' main brief (Paper No. 20).

¹ Application filed September 28, 1994 for the reissue of U.S. Patent No. 5,151,019, granted on September 29, 1992, based on Application 07/430,851, filed November 2, 1989.

THE REJECTION

Claims 35 and 36 stand rejected under 35 U.S.C. § 251 as attempting to improperly recapture subject matter surrendered to obtain the patent sought to be reissued.

Reference is made to the appellants' main and reply briefs (Paper Nos. 20 and 24) and to the examiner's answer (Paper No. 21) for the respective positions of the appellants and the examiner with regard to the merits of this rejection.²

DISCUSSION

Reissue claims 35 and 36 are broadened versions of claims 1 and 2 in U.S. Patent No. 5,151,019.³ The record in U.S. Patent No. 5,151,019 shows the following with respect to the prosecution of claims 1 and 2.

A. On February 4, 1992, the examiner entered a final rejection (Paper No. 16) wherein claims 1 and 2 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,549,860 to Yakich in view of U.S. Patent No. 4,559,038 to Berg et al.

B. On April 7, 1992, the examiner held an interview with one of the applicants, Mr. Danby, and his counsel, Mr. Kuesters. The results of the interview were recorded by the examiner in an interview summary (Paper No. 18) which states in pertinent part that

Claim 1 is to be amended to add that members are arranged for controlled relative movement in opposed [sic, opposed] directions transverse [sic, transverse] to the tube. . . . Claim language read over Yasich [sic, Yakich] and Ger-

² Although the statement of rejection in the examiner's answer refers to "the equitable doctrine of recapture," the accompanying explanation indicates that the rejection is actually based on the provisions of 35 U.S.C. § 251. This is in accord with the prevailing view that the prohibition against the improper recapture of surrendered subject matter via reissue has statutory underpinnings. See, for example, *Hester Industries Inc. v. Stein Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998) and MPEP § 1412.02.

³ Allowed reissue claim 1 is identical to patent claim 1. Allowed reissue claim 2 is identical to patent claim 2 except for the inclusion of a phrase (not at issue here) which was inadvertently omitted from the patent due to a printing error.

man reference.⁴ Amendment will be entered.

C. On April 8, 1992, applicants' counsel filed a paper (Paper No. 19) amending claims 1 and 2 to specify, *inter alia*, that the deforming means of the claimed pumping device "comprises members arranged for controlled relative movement in opposed directions in parallel planes transverse to the direction of liquid passage within said tubing." In accompanying remarks, counsel stated that

Claim 1 submitted herewith differs slightly from the wording of the proposed Claim 1 discussed during the April 7, 1992 interview by the recitation that the members of the deforming means have controlled relative movement in — parallel planes — transverse to the direction of fluid flow consistent with the fact that the tubing is in fact deformed over a surface area defined by parallel planes, not a single plane, as otherwise suggested by the proposed claim language discussed during the April 7, 1992 interview. Claim 2 is amended herewith to incorporate the same changes added to Claim 1, thereby to define more definitively the patentably distinguishing structure of the claimed deforming means of Applicants' invention [page 5].

Counsel added that

[a]s explained during the April 7, 1992 interview, none of the prior art references of record, including the *Yakich* patent, teaches a deforming means including members arranged for controlled relative movement in opposed directions in parallel planes transverse to the direction of liquid passage, with the resulting operation as recited in the amended Claims 1 and 2 [pages 6 and 7].

D. On April 13, 1992, the examiner mailed a Notice of Allowability (Paper No. 20) indicating that all of the pending claims, including amended claims 1 and 2, were allowed.

The appellants filed the instant reissue application within two years from the grant of the original patent alleging that they had

⁴ The examiner identified the German reference elsewhere in the interview summary as German document 2939212 which had been cited in an information disclosure statement filed March 10, 1992 (Paper No. 17).

claimed less than they had a right to claim in the patent by not including claims having the scope of claims 35 and 36 of this reissue patent application. Claims 35 and 36 of the reissue application correspond to claims 1 and 2 of the patent with the exception of the description of the "deforming means". Claims 1 and 2 of the patent state that the deforming means comprises members arranged for controlled relative movement in opposed directions in parallel planes transverse to the direction of liquid passage within tubing. Claims 35 and 36 state that the deforming means comprises members arranged for controlled relative movement in opposed directions which extend transversely to the direction of liquid passage within said tubing [original and supplemental reissue declarations, paragraph 4].

Thus, reissue claims 35 and 36 differ from patent claims 1 and 2 (and from allowed reissue claims 1 and 2) in that they do not include the "in parallel planes" language inserted into the patent claims via the amendment filed April 8, 1992 which resulted in the issuance of the patent. In rejecting claims 35 and 36, the examiner takes the position that

the "parallel planes" limitation [was] deliberately added to claims in the application for the patent . . . upon which the present reissue . . . is based to overcome prior art and render those claims patentable. "Error" within the meaning of 35 U.S.C. § 251 does not include deliberate decisions to surrender specific subject matter in order to overcome prior art. Appellant's [sic] representative voluntarily added the "parallel planes" limitation to the claims in the final amendment of April 8, 1992 in order to overcome the prior art and define the patentable structure of the applicants' invention. Therefore, the reissue claims are an attempt to impermissibly recapture what the applicants surrendered in the original prosecution [answer, page 4].

The appellants, on the other hand, submit that the prosecution history of the application which matured into the patent clearly demonstrates that the "in parallel planes" language absent from reissue claims 35 and 36 was not added to patent claims 1 and 2 to overcome the prior art.

The recapture rule rooted in 35 U.S.C. § 251 prevents a patentee from regaining

through reissue subject matter surrendered in an effort to obtain allowance of original claims. *In re Clement*, 131 F.3d 1464, 1468-69, 45 USPQ2d 1161, 1164 (Fed. Cir. 1997). The first step in applying the recapture rule is to determine whether and in what aspect the reissue claims are broader than the patent claims; the second step is to determine whether the broader aspects of the reissue claims relate to surrendered subject matter by looking to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection. *Id.*

The application of the first step to the present fact situation is fairly simple and straightforward and is not the subject of dispute. Reissue claims 35 and 36 are broader than corresponding patent claims 1 and 2 in that they do not include the "in parallel planes" language.

The controversy in this appeal involves the application of the second step, i.e., whether the "in parallel planes" language absent from claims 35 and 36 relates to subject matter surrendered in an effort to overcome the prior art and obtain allowance of patent claims 1 and 2. Based on our review of the patent's prosecution history, we are satisfied that the "in parallel planes" language does not relate to surrendered subject matter.

[1] The interview summary in the patent record fairly reflects an agreement between the examiner and counsel that claim 1, and by implication claim 2, would overcome the prior art if amended to include the limitation that the deforming means comprises members arranged for controlled relative movement in opposed directions transverse to the direction

of liquid passage within the tubing. The interview summary makes no mention of the additional "in parallel planes" limitation. The appellants subsequently added both limitations to claims 1 and 2 with the explanation that the "in parallel planes" limitation was consistent with the fact that the tubing is deformed over a surface area defined by parallel planes rather than a single plane. This is the only specific reason expressed in the prosecution history of the patent as to why the "in parallel planes" limitation was added to claims 1 and 2. There is nothing in the appellants' explanation or in any other part of the prosecution history which indicates that either the examiner or the appellants considered the "in parallel planes" limitation necessary to overcome the prior art. To infer otherwise from the remarks accompanying the amendment which mentioned both limitations in urging the patentability of claims 1 and 2 over the prior art would be unwarranted. Indeed, given the context of the "in parallel planes" limitation within the other added limitation, it would have been surprising had counsel not referred to both in arguing for the allowance of the claims.

In light of the foregoing, the absence of the "in parallel planes" language from reissue claims 35 and 36 does not pose a recapture problem. Accordingly, we shall not sustain the standing 35 U.S.C. § 251 rejection of these claims.

The decision of the examiner is reversed.

REVERSED